

Coordination with State Programs. The Panel recommended that EPA consider the impact of any new requirements on existing state programs and include in the proposed rule sufficient flexibility to accommodate such programs where they meet the minimum requirements of federal NPDES regulations. The Panel further recommended that EPA continue to consult with states in an effort to promote compatibility between federal and state programs. EPA has consulted with states. There were seven states represented on the CAFO workgroup (see Section XII.G.1). In addition, EPA asked for comment on the proposed options from nine national associations that represent state and local government officials. (See Section XIII.G.) In conducting its analyses for this rulemaking, EPA accounted for requirements under existing state programs. A summary of EPA's estimated costs to the NPDES Permitting Authority are presented in Section X.G.1 and Section XIII.B.

XIII. Administrative Requirements

A. Executive Order 12866: "Regulatory Planning and Review"

Under Executive Order 12866 [58 FR 51735, October 4, 1993], the Agency must determine whether the regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

- (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
- (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order."

It has been determined that this proposed rule is a "significant regulatory action" under the terms of Executive Order 12866. As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

B. Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.

The RFA generally requires an agency to prepare a regulatory flexibility analysis for any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a

substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

The RFA provides default definitions for each type of small entity. It also authorizes an agency to use alternative definitions for each category of small entity, “which are appropriate to the activities of the agency” after proposing the alternative definition in the *Federal Register* and taking comment. 5 U.S.C. §601(3)-(5). In addition to the above, to establish an alternative small business definition, agencies must consult with the Small Business Administration (SBA) Chief Counsel for Advocacy.

For purposes of assessing the impacts of today’s rule on small entities, small entity is defined as: (1) a small business based on annual revenue standards established by SBA, with the exception of one of the six industry sectors where an alternative definition to SBA’s is proposed; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

The definitions of small business for the livestock and poultry industries are in SBA’s regulations at 13 CFR 121.201. These size standards were updated in September, 2000. SBA size standards for these industries define a “small business” as one with average revenues over a 3-year period of less than \$0.5 million annually for dairy, hog, broiler, and turkey operations, \$1.5 million for beef feedlots, and \$9.0 million for egg operations. In today’s rule, EPA is proposing to define a “small” egg laying operation for purposes of its regulatory flexibility assessments under the RFA as an operation that generates less than \$1.5 million in annual revenue. Because this definition of small business is not the definition established under the RFA, EPA is specifically seeking comment on the use of this alternative definition as part of today’s notice of the proposed rulemaking. EPA has consulted with the SBA Chief Counsel for Advocacy on the use of this alternative definition. EPA believes this definition better reflects the agricultural community’s sense of what constitutes a small business and more closely aligns with the small business definitions codified by SBA for other animal operations. A summary of EPA’s analysis pertaining to the alternative definition is provided in Section 9 of the *Economic Analysis*. A summary of EPA’s consultation with SBA is provided in the record.

In accordance with Section 603 of the RFA, EPA prepared an initial regulatory flexibility analysis (IRFA) that examines the impact of the proposed rule on small entities along with regulatory alternatives that could reduce that impact. The IRFA is available for review in the docket (see Section 9 of the *Economic Analysis*). This analysis is summarized in Section X.J of this preamble. Based on available information, there are no small governmental operations or nonprofit organizations that operate animal feeding operations that will be affected by today’s proposed regulations.

The majority (95 percent) of the estimated 376,000 AFOs are small businesses, as defined by SBA. Of these, EPA estimates that there are 10,550 operations that will be subject to the proposed requirements that are small businesses under the two-tier structure. Under the three-tier structure, an estimated 14,630 affected operations are small businesses. The difference in the number of affected

small businesses is among poultry producers, particularly broiler operations. Section X.J.2 provides additional detail on how EPA estimated the number of small businesses.

Based on the IRFA, EPA is proposing concludes that the proposed regulations are economically achievable to small businesses in the livestock and poultry sectors. EPA's economic analysis concludes that the proposed requirements will not result in financial stress to small businesses in the veal, dairy, hog, turkey, and egg sectors. However, EPA's analysis concludes that the proposed regulations may result in financial stress to 150 to 280 small broiler operations under the two-tier and three-tier structure, respectively. In addition, EPA estimates that 10 to 40 small beef and heifer operations may also experience financial stress under each of the proposed tier structures. EPA considers these operations— comprising about 2 percent of all affected small CAFO businesses—may be vulnerable to closure. Details of this economic assessment are provided in Section X.J.

EPA believes that moderate financial impacts that may be imposed on some operations in some sectors is justified given the magnitude of the documented environmental problems associated with animal feeding operations, as described in Section V of this document. Section IV further summarizes EPA's rationale for revising the existing regulations, including: (1) address reports of continued discharge and runoff from livestock and poultry operations in spite of the existing requirements; (2) update the existing regulations to reflect structural changes in these industries over the last few decades; and (3) improve the effectiveness of the existing regulations. Additional discussion of the objectives of and legal basis for the proposed rule is presented in Sections I through III.

Section XIII.F summarizes the expected reporting and recordkeeping requirements required under the proposed regulation based on information compiled as part of the Information Collection Request (ICR) document prepared by EPA.

Section X.J.4 summarizes the principal regulatory accommodations that are expected to mitigate future impacts to small businesses under the proposed regulations. Under both of the co-proposed alternatives, EPA is proposing to eliminate the "mixed" animal calculation for operations with more than a single animal type for determining which AFOs are CAFOs. As a result, smaller operations that house a mixture of animal types where none of these animal types independently meets the regulatory threshold are not considered CAFOs under today's proposed rulemaking, unless they are individually designated. Additional accommodations are being proposed under the two-tier structure. Under the two-tier structure, EPA is proposing to establish a regulatory threshold that would define as CAFOs all operations with more than 500 AU. EPA is also considering a two-tier alternative that would define all operations with more than 750 AU as CAFOs. The two-tier structure would provide relief to small businesses since this would remove from the CAFO definition operations with between 300 AU and 500 AU (or 750 AU) that under the current rules may be defined as CAFOs. Also, under the two-tier structure, EPA is proposing to raise the size standard for defining egg laying operations as CAFOs. This alternative would remove from the CAFO definition egg operations with between 30,000 and 50,000 laying hens (or 75,000 hens) that under the current rules are defined as CAFOs, if they utilize a liquid

manure management system. Additional information on the regulatory relief provisions being proposed by EPA is provided in Section VII of this preamble.

As required by section 609(b) of the RFA, as amended by SBREFA, EPA also conducted outreach to small entities and convened a Small Business Advocacy Review Panel to obtain advice and recommendations from representatives of the small entities that potentially would be subject to the rule's requirements. Consistent with the RFA/SBREFA requirements, the Panel evaluated the assembled materials and small entity comments on issues related to the elements of the IRFA. A complete summary of the Panel's recommendations is provided in the *Final Report of the Small Business Advocacy Review Panel on EPA's Planned Proposed Rule on National Pollutant Discharge Elimination System (NPDES) and Effluent Limitations Guideline (Effluent Guidelines) Regulations for Concentrated Animal Feeding Operations* (April 7, 2000). This document is included in the public record. As documented in the panel report, the participants of the Small Business Advocacy Review Panel did not identify any Federal rules that duplicate or interfere with the requirements of the proposed regulation.

Section XII.G of this document provides a full summary of the Panel's activities and recommendations. This summary also describes each of the subsequent actions taken by the Agency, detailing how EPA addressed each of the Panel's recommendations. EPA is interested in receiving comments on all aspects of today's proposal and its impacts on small entities.

C. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), P.L. 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any one year.

Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative, if the Administrator publishes with the final rule an explanation why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the

development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that today's proposed regulations contain a Federal mandate that may result in expenditures of \$100 million or more for the private sector in any one year. Accordingly, EPA has prepared the written statement required by section 202 of the UMRA. This statement is contained in the *Economic Analysis* and also the *Benefits Analysis* for the rule. These support documents are contained in the record. In addition, EPA has determined that the rules contain no regulatory requirements that might significantly or uniquely affect small governments. Thus, today's rules are not subject to the requirements of section 203 of the UMRA. Additional information that supports this finding is provided below.

A detailed discussion of the objectives and legal basis for the proposed CAFO regulations is presented in Sections I and III of the preamble. A consent decree with the Natural Resources Defense Council established a deadline of December 2000 for EPA to propose effluent limitations for this industry.

EPA prepared several supporting analyses for the final rules. Throughout this preamble and in those supporting analyses, EPA has responded to the UMRA section 202 requirements. Costs, benefits, and regulatory alternatives are addressed in the *Economic Analysis* and the *Benefits Analysis* for the rule. These analyses are summarized in Section X and Section XI of this preamble. The results of these analyses are summarized below.

EPA prepared a qualitative and quantitative cost-benefit assessment of the Federal requirements imposed by today's final rules. In large part, the private sector, not State, local and tribal governments, will incur the costs of the proposed regulations. Under the two-tier structure, total annualized compliance costs to industry are projected at \$831 million (pre-tax)/\$572 million (post-tax). The cost to off-site recipients of CAFO manure is estimated at \$10 million per year. Under the three-tier structure, costs to industry are estimated at \$930 million per year (pre-tax)/\$658 million (post-tax), and the annual cost to off-site recipients of manure is estimated at \$11 million. This analysis is summarized in Section X.E.1 of this preamble.

Authorized States are expected to incur costs to implement the standards, but these costs will not exceed the thresholds established by UMRA. Under the two-tier structure, State and Federal administrative costs to implement the permit program are estimated to be \$6.2 million per year: \$5.9 million for States and \$350,000 for EPA. Under the three-tier structure, State and Federal administrative costs to implement the permit program are estimated by EPA at \$7.7 million per year, estimated at \$7.3 million for States and \$416,000 for EPA. This analysis is summarized in Section X.G.1 of this preamble. More detailed information is provided in the *Economic Analysis*. The Federal resources (i.e., water pollution control grants) that are generally available for financial assistance to States are included in Section 106 of the Clean Water Act. There are no Federal funds available to

defray the costs of this rule on local governments. Since these rules do not affect local or tribal governments, they will not result in significant or unique impacts to small governments.

Overall, under the two-tier structure, the projected total costs of the proposed regulations are \$847 million annually. Under the three-tier structure, total social costs are estimated at \$949 million annually.

The results of EPA's economic impact analysis show that the percentage of operations that would experience financial stress under each of the proposed tier structures represent 7 percent of all affected CAFOs (Section X.F.1). This analysis is conducted without taking into account possible financial assistance to agricultural producers that could offset the estimated compliance costs to CAFOs to comply with the proposed regulations, thus mitigating the estimated impacts to these operations. Federal programs, such as USDA's Environmental Quality Incentives Program (EQIP), and other State and local conservation programs provide cost-share and technical assistance to farmers and ranchers who install structural improvements and implement farm management practices, including many of the requirements that are being proposed today by EPA. EQIP funds are limited to livestock and poultry operations with fewer than 1,000 animal units (AUs), as defined by USDA, but could provide assistance to operations with less than 1,000 AU as well as to some larger operations in the poultry and hog sectors.

EPA also conducted an analysis that predicts and quantifies the broader market changes that may result due to compliance. This analysis examines changes throughout the economy as impacts are absorbed at various stages of the food marketing chain. The results of this analysis show that consumer and farm level price changes will be modest. This analysis is summarized in Section X.F.3.

EPA does not believe that there will be any disproportionate budgetary effects of the rules on any particular area of the country, particular types of communities, or particular industry segments. EPA's basis for this finding with respect to the private sector is addressed in Section 5 of the *Economic Analysis* based on an analysis of community level impact, which is summarized in Section X.G.2 of the preamble. EPA considered the costs, impacts, and other effects for specific regions and individual communities, and found no disproportionate budgetary effects. EPA's basis for this finding with respect to the public sector is available in the record.

The proposed mandate's benefits are primarily in the areas of reduced health risks and improved water quality. The *Benefits Analysis* supporting the rulemaking describes, qualitatively, many such benefits. The analysis then quantifies a subset of the benefits and, for a subset of the quantified benefits, EPA monetizes (i.e., places a dollar value on) selected benefits. EPA's estimates of the monetized benefits of the proposed regulations are estimated to range from \$146 million to \$165 million under the two-tier structure. Under the three-tier structure, estimated benefits range from \$163 million to \$182 million annually. This analysis is summarized in Section XI of this preamble.

EPA consulted with several States during development of the proposed rules. Some raised concerns that the national rule would have workload and cost implications for the State. Some States with implementation programs underway or planned want to have their programs satisfy the requirements of the proposed rule. Other States expressed concerns about the loss of cost-share funds to AFOs once they are designated as point sources. There were additional comments regarding inconsistencies with the Unified Strategy. See Section IX.A for a discussion of alternative State programs, Section X.G for a discussion of State costs and the workload analysis, Sections III.D and VII.B for a discussion of consistency with the AFO Strategy, and Section IX.E for a discussion of cost-share funds.

For the regulatory decisions in today's rules (allowing for the options reflected by the co-proposal), EPA has selected alternatives that are consistent with the requirements of UMRA in terms of cost, cost-effectiveness, and burden. The proposal is also consistent with the requirements of the CWA. This satisfies section 205 of the UMRA. As part of this rulemaking, EPA had identified and considered a reasonable number of regulatory alternatives. (See Section VII for NPDES Scenarios and Section VIII for effluent guidelines technology options). Section X.E compares the costs across these alternatives. Section X.H provides a cost-effectiveness analysis that shows that the proposed BAT Option is the most cost-effective of these alternatives. Sections VII and VIII of the preamble are devoted to describing the Agency's rationale for each regulatory decision. Section IV of this document further summarizes EPA's rationale for revising the existing regulations.

D. Executive Order 13045: "Protection of Children from Environmental Health Risks and Safety Risks"

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be "economically significant" as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health and safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This proposed rule is subject to E.O. 13045 because it is an economically significant regulatory action as defined by E.O. 12866, and we believe that the environmental health or safety risks addressed by this action have or may have disproportionate effects on children. Accordingly, we have evaluated, to the extent possible, the environmental health or safety effects of pollutants from CAFOs on children. The results of this evaluation are contained in sections V.C and XI.B of the preamble as well as the Environmental Assessment and Benefits Assessment (these documents have been placed in the public docket for the rule).

The Agency believes that the following pollutants have or may have a disproportionate risk to children: nitrates, pathogens, trace metals such as zinc, arsenic, copper, and selenium, pesticides, hormones, and endocrine disruptors. These health risks are summarized in Section V.C and described in detail in the Environmental Assessment. With the exception of nitrates in drinking water, the Agency

has very little of the detailed information necessary to conduct an assessment of these risks to children for these pollutants. The Agency solicits risk and exposure data and models that could be used to characterize the risks to children's health from CAFO pollutants.

There is evidence that infants under the age of six months may be at risk from methemoglobinemia caused by nitrates in private drinking water wells, typically when ingesting water with nitrate levels higher than 10 micrograms/liter. The Agency only has enough information to determine that a chronic dose of 10 micrograms/liter may cause an adverse health effect, but there is no dose-response function for nitrates, nor does the Agency have other information necessary to conduct a detailed health risk assessment (for example, the actual number of cases of methemoglobinemia are not reported and are thus highly uncertain). Instead, the Agency has estimated the reduction in the number of households that will be exposed to drinking water with nitrate levels above 10 micrograms/liter in Chapter 8 of the Benefits Assessment (noting that the Agency does not have information on the number of households exposed to nitrates that also have infants). The Agency assumes that nitrate levels lower than 10 micrograms/liter pose no risk of methemoglobinemia.

The Agency estimates that there are approximately 13.5 million households with drinking water wells in counties with animal feeding operations. Of these, the Agency estimates that approximately 1.3 million households are exposed to nitrate levels above 10 micrograms/liter. The Agency further estimates that approximately 166,000 households would have their nitrate levels brought below 10 micrograms/liter under the two-tier structure. Approximately 161,000 households would have their nitrate levels brought below 10 micrograms/liter under the three-tier structure. Furthermore, the Agency estimates that options more stringent than those proposed would have small incremental changes in pollutant loadings to groundwater (see the Technical Development Document). Thus, the Agency expects the number of additional households protected from nitrate levels greater than 10 micrograms/liter would be negligible under more stringent options. The Agency therefore does not believe that requirements more stringent than those proposed would provide meaningful additional protection of children's health risks from methemoglobinemia. Furthermore, the Agency is only able to regulate groundwater quality through NPDES permits if there is a direct hydrologic connection to surface water (see Section VII.C.2.j).

Methemoglobinemia is only one children's health risk caused by CAFO pollutants, as discussed above, in Section V.C, and elsewhere in the record. It was the only risk to children's health which the Agency was able to quantify (if incompletely) in any way. The options considered by the Agency, as well as the rationale for the proposed options, are discussed in detail in Sections VII and VIII of this preamble. To the extent possible under the authority of the CWA, EPA chose options that were protective of environmental and human health, including children's health. These option selections were based on the best risk assessments possible given the limited data available. The public is invited to submit or identify peer-reviewed studies and data, of which the Agency might not be aware that assessed results of early life exposure to nitrates or any other pollutant discharged by CAFOS.

E. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments nor imposes substantial direct compliance costs on them. First, there are currently no tribal governments that have been authorized to issue NPDES permits. Thus, there will be no burden to tribal governments. Second, few CAFO operations are located on tribal land. Therefore, compliance costs to tribal communities will not be significant. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

However, EPA has let tribal communities know about this rulemaking through a presentation of potential rule changes at the National Environmental Justice Advisory Committee meeting in Atlanta in June, 2000 and through notices in tribal publications.

F. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. An Information Collection Request (ICR) document has been prepared by EPA (ICR No. 1989.01) and a copy may be obtained from Sandy Farmer by mail at Collection Strategies Division; U.S. Environmental Protection Agency (2822); 1200 Pennsylvania Ave., NW, Washington, DC 20460, by email at farmer.sandy@epamail.epa.gov, or by calling (202) 260-2740. A copy may also be downloaded off the internet at <http://www.epa.gov/icr>.

Today's proposed rule would require all animal feeding operations (AFOs) that meet the proposed CAFO definition to apply for a permit and develop a certified permit nutrient plan and to implement that plan. Implementation of the plan includes the cost of recording animal inventories, manure generation, field application of manure and other nutrients (amount, rate, method, incorporation, dates), manure and soil analysis compilation, crop yield goals and harvested yields, crop rotations, tillage practices, rainfall and irrigation, lime applications, findings from visual inspections of feedlot areas and

fields, lagoon emptying, and other activities on a monthly basis. Records may include manure spreader calibration worksheets, manure application worksheets, maintenance logs, and soil and manure test results.

The average annual burden for this rule covering both the private and public sector for the three-tiered option is 1.6 million hours and \$37 million annually; for the two-tiered option, burden is 1.2 million hours annually at \$29 million annually. These values do not account for State programs that may already be requiring some of the recordkeeping and reporting requirements already. Thus, this burden would be an overestimate to the degree that some States already require such actions.

For the three-tiered structure, the average annual CAFO burden is estimated to be 80 hours with the frequency of responses based on requirements ranging from two times per year to once every five years. There are 19,519 likely CAFO respondents and 28 states. Under this scenario, the state annual average burden is estimated at 3,214 hours. The average annual operation and maintenance costs are estimated at \$4.3 million for CAFOs and \$60,000 for States; labor costs are estimated at \$28.9 million for CAFOs and \$2.6 million for States; capital costs are estimated at \$1.6 million for CAFOs and \$0.0 for States.

For the two-tiered structure, CAFO average annual burden per respondent is 81 hours and the State burden is 2,500 hours. There are 15,015 likely CAFO respondents and 28 states. The 28 state count is an average over three years assuming that half the delegated states will have a program established in year one, half in year 2 and all in year three. Average annual operation and maintenance costs are \$3.3 million for CAFOs and \$60,000 for States; labor costs are \$22.6 million for CAFOs and \$2.0 million for States; capital costs are \$1.3 million for CAFOs and \$0.0 for States.

The burden required for this rulemaking will allow EPA to determine whether a CAFO operator is monitoring his waste management system in an environmentally safe way. This data will be used to assess compliance with the rule and help determine enforcement cases. The Permit Nutrient Plan data requirements ensure that the CAFO owner has established the appropriate application rate for their fields on which they spread manure; is providing adequate operation and maintenance for the storage area and feedlot, and is meeting the requirements to keep agriculture waste out of the Nation's waters. The information requested herein is mandatory (33 U.S.C. 1318 (Section 308 of the Clean Water Act)). The Agency is requesting comment in this proposal on how much, if any of this information should be confidential business information.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. Burden estimates include the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or

otherwise disclose the information. Additional burden has been estimated for off-site recipients who must certify that they are applying manure in an appropriate manner.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless the collection form displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

Comments are requested on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques. Send comments on the ICR to the Director, Collection Strategies Division; U.S. Environmental Protection Agency (2822); 1200 Pennsylvania Ave., NW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., N.W., Washington, DC 20503, marked "Attention: Desk Officer for EPA." Include the ICR number in any correspondence. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after **[Insert date of publication in the FEDERAL REGISTER]**, a comment to OMB is best assured of having its full effect if OMB receives it by **[Insert date 30 days after publication in the FEDERAL REGISTER]**. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

G. Executive Order 13132: "Federalism"

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have Federalism implications." "Policies that have Federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

This proposed rule does not have Federalism implications. It will not have substantial direct effects on the States, on this relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. EPA estimates that the average annual impact on all authorized States together is \$6.0 million. EPA does not consider an annual impact of \$6 million on States a substantial effect. In addition, EPA does not expect this rule to have any impact on local governments.

Further, the revised regulations would not alter the basic State-Federal scheme established in the Clean Water Act under which EPA authorizes States to carry out the NPDES permitting program. EPA expects the revised regulations to have little effect on the relationship between, or the distribution of power and responsibilities among, the Federal and State governments. Thus, Executive Order 13132 does not apply to this rule.

In the spirit of Executive Order 13132, and consistent with EPA policy, EPA consulted with representatives of State and local governments in developing this proposed rule. EPA sent a summary package outlining the proposed changes to the State and local associations that represent elected officials including the National Governor's Association, National Conference of State Legislators, U.S. Conference of Mayors, Council of State Governments, International City/County Management Association, National Association of Counties, National Association of Towns and Townships, and County Executives of America. In addition, as discussed in Section XII.F., there was State representation on the CAFO Regulation Workgroup.

EPA received four responses from these national associations, the National Governor's Council, the National League of Cities, the National Council of State Legislators and the National Association of Conservation Districts. EPA also received a letter from the Governor of Delaware and the Delaware Congressional delegation. The National Governor's Association (NGA), the National League of Cities (NLC) and the National Association of Conservation Districts (NACD) disagree with EPA's assessment that the rule would have minimal impact on the States. Except for this issue, the NLC supported the rule package especially the coverage of poultry and immature animals, the clarification of stormwater runoff exemptions, the lower threshold, and the seven strategic issues EPA listed to address pollution from animal feeding operations. NLC encouraged EPA to exercise its authority to issue NPDES permits where a delegated State has not taken appropriate action.

NGA and Delaware want the flexibility to design functionally equivalent programs. NGA and NACD expressed concern regarding lowering the threshold as this would bring in more entities to be permitted and the States already have a permit backlog. In addition, they are concerned that 319 and EQIP funds will no longer be available to operations that are defined as CAFOs. Another concern is the elimination of the 25 year/24 hour exemption. NGA comments address the burden on the State permitting authority (backlog issue) and the unfairness of facilities that work with states to eliminate discharges would still have to get a permit. On the issue of adequate public involvement in general permits as well as the site specific requirements of the Effluent Limitation Guideline, NGA is concerned the advantage of general permits as a time saver for the states may be lost. In response to NGA's concerns, EPA met with NGA and discussed the package and its potential impacts. EPA, also upon request, met with the National Association of State Legislators to review the package and answer their questions. (See Section IX for discussion of alternative State programs. See Section VII.B for a discussion of rule scope. See Section X.G for costs to permitting authorities. See Section VII.C for discussion of the 25 year/24 hour storm exemption. See Section VII.E for discussion of public involvement.)

The primary concern raised by the States represented on the CAFO Regulation Workgroup was to clarify and simplify the rules to make them more understandable and easier to implement. Many of the proposed changes were made with this objective in mind. Also, the States wanted EPA to accept functionally equivalent State programs. To address this concern, as stated in the Joint Unified USDA/EPA AFO Strategy (see "Strategic Issue #3"), where a State can demonstrate that its program meets the requirements of an NPDES program consistent with 40 CFR Part 123, EPA is proposing to

amend the current NPDES authorization to recognize the State program. In addition, States were concerned about the cost of implementing any changes to the program. EPA believes the costs to the States for implementing this proposed rule will not be high. EPA is assuming that all States will adopt the sample general permit. Some States already have a general permit that would just need to be modified.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

H. Executive Order 12898: “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations”

The requirements of the Environmental Justice Executive Order are that ...”EPA will... review the environmental effects of major Federal actions significantly affecting the quality of the human environment. For such actions, EPA reviewers will focus on the spatial distribution of human health, social and economic effects to ensure that agency decisionmakers are aware of the extent to which those impacts fall disproportionately on covered communities.” EPA has determined that this rulemaking is economically significant. However, the Agency does not believe this rulemaking will have a disproportionate effect on minority or low income communities. The proposed regulation will reduce the negative affects of CAFO waste in our nation’s waters to benefit all of society, including minority communities.

The National Environmental Justice Advisory Committee (NEJAC) submitted a set of recommendations to EPA regarding CAFOs that included recommendations to be addressed in revisions to EPA’s regulations for CAFO’s. Each recommendation is addressed below.

The NEJAC recommended that EPA “promulgate new, effective regulations that set uniform, minimum rules for all AFOs and CAFOs in the United States.” In response, EPA believes that today’s proposed rule revisions would represent new, uniform and effective requirements for CAFOs (AFOs by definition are not point sources and so would not be subject to today’s proposed CAFO rules).

The Committee requested that EPA impose a zero discharge standard on runoff from land application of CAFO wastes. For the reasons described in section VIII. C.3., BAT Options Considered, of today’s notice, EPA believes it is not appropriate to set a technology-based standard at this level with respect to land application runoff.

NEJAC requested that EPA prohibit or restrict the siting of facilities in certain areas such as flood plains. Siting of private industry is primarily a local issue and should be addressed at the local level. Discharge limitations proposed today should, however, discourage operators from locating in flood plains. Proposed requirements for swine, veal and poultry CAFOs would require no discharge under any circumstances. Beef and dairy CAFOs would have to comply with zero discharge except in the event of a chronic or catastrophic storm which exceeds the 25 year, 24 hour storm. If existing

operations are located in flood plains it is in their best interest to divert uncontaminated storm water away from their production area to avoid inundation of the production area and potential breaching of their manure storage system during flood events. EPA proposes to prohibit manure application to crop or pasture land within 100 feet of surface waters, tile intake structures, agricultural drainage wells, and sinkholes which will also minimize the risk of discharge under flood conditions.

NEJAC requested monitoring requirements in the rule. EPA has proposed an appropriate set of monitoring requirements to be included in CAFO permits (See section XIII of today's notice).

NEJAC also requested public notification of the construction or expansion of CAFOs or issuance of permits. Under today's proposed rules, EPA would require individual permits, which are subject to individual public notice and comment, for facilities that are located in an environmentally sensitive area; have a history of operational or compliance problems; are an exceptionally large or significantly expanding facility; or where the Director is aware of significant public concern about water quality impacts from the CAFO. For all other facilities that are to be covered by general permits, for purposes of public notice, today's proposal would require the permitting authority to publish on a quarterly basis its receipt of Notices of Intent (NOIs) submitted by CAFOs.

NEJAC further recommended that EPA require States and tribes to develop inspection programs that allow unannounced inspections of all CAFOs and to make these programs available for public comment. This concern is already addressed by existing Clean Water Act requirements. Specifically, under the Act, EPA may conduct unannounced inspections, and States must have the authority to inspect to the same extent as EPA. Although there is no specific requirement that State inspection plans be made publicly available, they may be available under State law.

NEJAC requested that EPA require the adoption of non-lagoon technology. Section XIII of today's notice describes the control technologies that EPA has investigated and which ones EPA proposes to identify in these regulations as the best available technologies. As described in Section XIII, this proposal finds that it would not be appropriate to prohibit the use of lagoon technologies.

NEJAC recommended requiring States and tribes to implement remediation programs for phased-out CAFO operations. In today's proposed rule, EPA proposes to require a CAFO to remain under permit coverage until it no longer has the potential to discharge manure or associated wastewaters..

Finally, NEJAC recommended that EPA impose stringent penalties on violating facilities. The Clean Water Act provides authority to subject violators to substantial penalties. The issue of which penalties are appropriate to impose in individual situations is beyond the scope of this rulemaking.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995, (Pub L. No. 104-113 Sec. 12(d) 15 U.S.C. 272 note) directs EPA to use voluntary consensus

standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standard bodies. The NTTAA directs EPA to provide Congress, through the Office of Management and Budget (OMB), explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This rulemaking involves technical standards. The rule requires operations defined as CAFOs in the beef and dairy subcategories to monitor groundwater for total dissolved solids (TDS), total chlorides, fecal coliform, total coliform, ammonia-nitrogen and TKN. EPA performed a search to identify potentially voluntary consensus standards that could be used to measure the analytes in today's proposed guideline. EPA's search revealed that consensus standards exist and are already specified in the tables at 40 CFR Part 136.3 for measurement of many of the analytes. All pollutants in today's proposed rule have voluntary consensus methods. EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially-applicable voluntary consensus standards and to explain why such standards should be used in this regulation.

XIV. Solicitation of Comments

A. Specific Solicitation of Comment and Data

EPA solicits comments on all aspects of today's proposal. In addition, throughout this preamble, EPA has solicited specific comments and data on many individual topics. The Agency reiterates its interest in receiving comments and data on the following issues:

1. EPA solicits comment on the use of a two tier structure based on lowering the existing 1,000 animal unit threshold to 500 for determining which AFOs are defined as CAFOs, and the elimination of the existing 300 to 1,000 animal unit category. EPA also solicits comment on the effect of a 500 AU threshold on the horse, sheep, lamb and duck sectors, as well as on the use of a 750 animal unit threshold for all sectors.
2. EPA solicits comment on the use of a three tier structure, including the proposed criteria that could result in an AFO in the middle Group being defined as a CAFO and on whether to use different criteria that provide more flexibility than those in today's proposal.
3. EPA solicits comment on revising the requirements for designation to eliminate the direct contact and man-made device criteria from the designation requirements of the CAFO regulations, and allow the designation of CAFOs by EPA in States with NPDES authorized programs. EPA also solicits comment on whether or not to eliminate the "on-site" requirement for conducting inspections and, instead, allow other forms of site-specific information gathering to be used.
4. EPA solicits comment on its proposal to clarify the definition of an AFO to clearly distinguish feedlots from pasture land and clarify coverage of winter feeding operations.